FDA Preliminary Public Health Notification*:

GAMBRO PRISMA ® CONTINUOUS RENAL REPLACEMENT SYSTEM

(You are encouraged to copy and distribute this information)

Issued: August 23, 2005

Dear Renal Dialysis Caregivers:

This is to alert you to the danger of not responding adequately to any of the "Incorrect Weight Change Detected" alarms of the Gambro Prisma® Continuous Renal Replacement System, and to recommend specific actions to prevent injuring patients. Gambro Renal Products, Inc. and FDA have determined that several serious injuries and deaths have occurred when users did not respond appropriately to one or more of the "***Incorrect Weight Change Detected"*** alarms (Effluent Weight, Replacement Solution Weight, or Dialysate Weight). These alarms are designed to alert the user when a potential fluid imbalance has occurred during the course of Continuous Renal Replacement Therapy (CRRT). If these alarms are ignored, an excessive amount of fluid can be removed from or administered to the patient.

You MUST NEVER override any of these alarms without first identifying and removing the cause of each alarm.

Recommendations

You must pay particular attention to the "***Incorrect Weight Change Detected***" alarms. It is critical to correct the problem if one or more of the "***Incorrect Weight Change Detected***" alarms (Effluent Weight, Replacement Solution Weight, or Dialysate Weight) occurs. The treatment MUST be discontinued and another device used if alarm conditions continue after intervention or the cause cannot be identified.

Refer to The Prisma® System Operator's Manual for detailed instructions. The table below is an excerpt from the Manual with instructions for correcting various conditions that may cause the "Incorrect Weight Change Detected" alarm for dialysate weight. Similar instructions are available for each of the other alarms.

Observation	Possible Cause(s)	Operator Response
Dialysate Weight (Incorrect weight change detected.)	Leaking or clamped dialysate line or bag; bag is swinging on scale hook.	Remedy; press CONTINUE.
	Room temperature variations are	Call for service.

	greater than ± 3°C (5.4°F) from the temperature at which the scales were calibrated.	
	Foreign object on dialysate scale.	Remove object; press CONTINUE
	Dialysate bag partially supported (not freely hanging).	Remove partial support; press CONTINUE.
	Seal on dialysate bag not completely broken.	Using aseptic technique, manipulate bag seal to provide unobstructed fluid pathway.
	Cartridge of the Prisma Set is dislodged from the cartridge carrier.	Press cartridge into cartridge carrier; Press CONTINUE Note: STOP softkey is available for use in above steps, if desired [a]
	Dialysate scale failed; internal malfunction.	Press STOP and end the treatment. Call for service.

[a] Pressing STOP stops all pumps, clears the alarm, and displays the Stop screen. The following options are available: resume treatment, change set, end treatment, or temporarily disconnect patient from the set.

Users are able to reduce the risk of these events by following the manufacturer's "Instructions for Use," Operator's Manual and User Interface of the Prisma® System. It is especially important to:

- handle each solution bag connection with care;
- properly spike each bag and/or properly break each frangible pin; and,
- hang each bag correctly on the related scale to guarantee that solution flows freely at the prescribed pump flow rate.

Background

The Prisma® device is a type of kidney hemodialysis system used for CRRT in critically ill patients. Approximately 5,000 have been distributed to hospitals worldwide, including 1,900 systems in the United States. The injuries and deaths have resulted because of excessive ultrafiltration (fluid being removed from the patient's body). This problem can occur when the causes of the "Incorrect Weight Change Detected" alarms are not adequately corrected by the user. The exact number of serious injuries and deaths are not known at this time because the firm and FDA are currently reviewing the data.

The firm, Gambro Renal Products Inc., issued a press release on August 16 and is distributing a "Worldwide Safety Alert" to all users of the Prisma® System explaining what actions to take to reduce the potential for risks associated with the device. Gambro is also issuing a follow up to the worldwide safety alert providing users with:

(1) warning labels to be affixed to all machines;
(2) an addendum to the Operator's Manual, including the additional warning; and

(3) a training program to educate users on how to avoid/troubleshoot this problem.

FDA is working closely with the firm to ensure that these documents contain appropriate information.

Contacting Gambro

You can direct questions about the Prisma System or requests for a copy of the Operator's Manual to Gambro Renal Products, Inc., Intensive Care Therapy Specialists at 1-800-525-2623.

Reporting to FDA

To report your experience regarding the devices in this Notification, please use MedWatch, the FDA's voluntary reporting program. You may submit reports to MedWatch by phone at 1-800-FDA-1088; by FAX at 1-800-FDA-0178; by mail to MedWatch, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857-9787; or online at http://www.fda.gov/medwatch/report.htm.

Getting More Information

If you have questions about this notification, please contact the Office of Surveillance and Biometrics (HFZ-510), 1350 Piccard Drive, Rockville, Maryland, 20850, by Fax at 301-594-2968, or by e-mail at phann@cdrh.fda.gov. You may also leave a voicemail message at 301-594-0650 and we will return your call as soon as possible.

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Sincerely yours,

Daniel Schultz, MD
Director
Center for Devices and Radiological Health
Food and Drug Administration

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